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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/596,237

06/05/2006

Karin Golz-Berner

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EXAMINER

BUCKLEY, AUDREA

ART UNIT

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1611

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11/12/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/596,237	Applicant(s) GOLZ-BERNER ET AL.	
	Examiner AUDREA J. BUCKLEY	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-31 is/are pending in the application.
- 4a) Of the above claim(s) 28 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-27, 30 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/5/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Applicant's arguments of 9/29/2009 in response to the election requirement of 8/17/2009 have been considered. Applicant's position that PCT Rule 13 permits the inclusion of both product claims and process claims specially adapted for the manufacture of the product is not considered persuasive. Applicant's arguments that the instantly claimed composition does not lack an inventive step have been considered, however since a 'special technical feature' is something that contributes over the art with regard to inventive step, lack of unity is established as further demonstrated by the prior art cited below (e.g., see the 102(b) rejection against the broadest product claim). Claims 17-27, 30, and 31 are examined on the merits herein.

Priority

This application claims the foreign priority date of Germany 103 58 306.8, filed 12/08/2003. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 6/5/2006 was filed on the mailing date of the application. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 is vague and indefinite because the metes and bounds of the term “wherein the carrier system is loaded four weeks after the loading with an oxygen content of 25-40% by volume of the initial oxygen content” are unclear. The phrase is unclear in that it can be interpreted in two different ways: (i) requiring an additional step where, at post-loading, the carrier system is again loaded with additional oxygen, or (ii) as a functional limitation where, at four weeks post-loading, the carrier composition comprises between 25-40% of the initial oxygen content by volume. It would be remedial to amend the claim to clearly distinguish between these two distinct interpretations of the instant claim language.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17, 18, 20, 23, 24, 26, and 31 are rejected under 35

U.S.C. 102(b) as being anticipated by Stora (US 6,403,109) as evidenced by Critical Care Medicine Tutorials (web archive 2002, accessed 11/9/2009).

Regarding claims 17, 20, 23, 24, and 26, Stora teaches perfume compositions free of organic solvents, existing in emulsified form, and capable of delivering the active agent to the skin (see abstract, in particular). Example 1 teaches a formulation comprising 2.23% perfluorodecaline, a fluorinated hydrocarbon; 24.93% Silicon DC® 345, a silicone polymer; and 10.05% of a perfuming oil base; the perfluorodecaline is the oxygen carrier system as in instant claims 1 and 24. Further, the instantly claimed partial pressure of gaseous oxygen is an inherent property since the atmospheric partial pressure of oxygen necessarily lies within the instantly claimed range. As stated in the Critical Care Medicine Tutorials, oxygen, being a gas, exerts a partial pressure, which is determined by the prevailing environmental pressure and, at sea level, is 159 mmHg, a value which falls within the instantly claimed range of 150-950 mbar (a range equal to 112.542 – 712.766 mmHg).

As to claim 18, the functional limitation of oxygen content inherently would lie within the range of 25-40% upon loading according to the instant specification. For example, page 2 of the instant specification (paragraph 5) describes the oxygen loading in which oxygen gas within a broad range of partial pressures is bubbled through the carrier system with stirring at ambient temperature for a

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specified time period. Upon bubbling oxygen through the carrier composition as described, the oxygen presence necessarily would result in an oxygen quantity equal to or approximating the quantity instantly claimed.

As to claim 31, Stora teach topically applicable emulsions with controlled refractive indices and viscosity values. Therefore, these emulsions are formed as topically applicable creams and/or gels (see column 2, lines 3 -48).

As such, Stora anticipates all of the features and limitations of instant claims 17, 18, 20, 23, 24, 26, and 31.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that

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the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stora (US 6,403,109).

Stora teaches perfume compositions free of organic solvents, existing in emulsified form, and capable of delivering the active agent to the skin (see abstract, in particular). Example 1 teaches a formulation comprising 2.23% perfluorodecaline, a fluorinated hydrocarbon; 24.93% Silicon DC® 345, a silicone polymer fluid; and 10.05% of a perfuming oil base; the perfluorodecaline is the oxygen carrier system. In a separate embodiment, Stora teaches that the liquid silicone polymer is present at a value of 55.12% by weight (see column 9, Example 3) while the perfluorodecaline and perfuming oil base remain constant.

As to claim 30, Stora does not teach an embodiment in which the silicone oil component of the liquid silicone polymer expressly is present in a quantity between 5 and 25% by weight.

Nonetheless, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the presence of the

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silicon fluid in order to optimize the physical and chemical properties of the target product based on the suggestion provided by Stora in Example 5, in particular.

One would have been motivated to do so in order to improve upon what is already generally known as taught by Stora and, the normal desire of scientists and artisans is to perform this routine optimization procedure. As addressed in MPEP 2144.05,

“Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Similarly, a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985).

Therefore, the instant claims lack patentable weight.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stora (US 6,403,109) in view of Gross *et al.* (US 5,637,318, hereinafter the “318 reference”).

The teachings of Stora are delineated above.

Stora do not teach a quantitative value for oxygen loading in a perfluorinated hydrocarbon carrier as in the instant claim.

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Nonetheless, the skilled artisan would have found the routine optimization of oxygen saturation of the oxygen carrier to have been normal scientific inquiry towards the optimization of the final product for the product's intended purpose of cosmetic application. Gross *et al.* ('318) teach oxygen-laden fluorocarbons and fluorocarbon mixtures suitable for dermatological use (see abstract, in particular). Additionally, Gross *et al.* state that fluorocarbons are capable of transporting oxygen (see '318 reference, column 2, line 39) and with the aid of known oxygen gas solubilities, the vapor pressure (an inherent property), and the critical solubility temperature, the loading of fluorocarbons with oxygen can be adjusted by the skilled artisan (see '318 reference, column 4, lines 21-26).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art to adjust the presence of oxygen in a fluorocarbon carrier for a dermatological application as suggested by Gross *et al.* in order to improve the oxygen carrying capacity of a topically applicable composition such as the one taught by Stora. One would have been motivated to do so in order to optimize the benefits associated with oxygen delivery to the skin as evaluated according to the final product. Since this optimization process would have been routine procedure, the skilled artisan would have expected resulting success.

Claims 21, 22, 25, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stora (US 6,403,109) in view of Gross *et al.* (US 5,643,601, (hereinafter, the '601 reference)).

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The teachings of Stora are delineated above. As to claim 22, Stora teach that the perfuming ingredients can belong to a variety of chemical classes including alcohols, esters, acetates, terpenic hydrocarbons, and essential oils of natural or synthetic origin (see column 5, lines 54-60).

Regarding claim 21, Stora does not expressly include a gelling or thickening agent in the carrier system. As to claim 22, Stora does not limit the carrier system oil base to one which is a vegetable oil, an ester, or a mixture thereof. Regarding claim 25, although Stora teaches embodiments in which the oxygen carrier system is both above and below the instantly claimed range of 6-10%, Stora does not teach an embodiment having the oxygen carrier system present in this quantity. Regarding claims 27, Stora does not teach an oxygen carrier system in a quantitative presence as instantly claimed.

However, Gross *et al.* ('601) teach phospholipid-and fluorocarbon containing cosmetics to be formulated as gels, creams, lotions, etc. in order to supply adequate oxygen to the skin upon application (see abstract, in particular). Gross *et al.* teach that the fluorocarbons in this composition analogous to that of Stora can be selected for oxygen gas solubility, partial vapor pressure, and lipid solubility according to the specific intended application ('601 reference, see column 3, lines 28-30). As to claims 27, Gross also refers to a prior teaching which indicates that cosmetic formulations containing oxygen gas include halogenated compounds for the intended purpose of acting as oxygen carriers (see '601 reference, column 1, lines 36-41). Gross names perfluorodecalin as a rapid release oxygen carrier which also is embodied in the invention (see '601

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reference, column 3, line 34; see also, column 4, Table 1). Specifically, Gross teaches an embodiment in which the formulation had reached the dermal skin section at which the oxygen partial pressure rose to a value of 159 mmHg after a penetration period. As to claim 21, Gross *et al.* teach the inclusion of hydroxyethyl cellulose, in a gel mask formulation of the invention (see '601 reference, column 7, example 9). As to claim 22, Gross *et al.* teach jojoba oil and liquid paraffin as components in Example 5, a body lotion. The skilled artisan would have recognized that jojoba oil is a liquid wax produced in the seed of the jojoba plant and is a mixture of wax esters desirably present in cosmetic and topical applications. As to claim 25, Gross teach an embodiment in which the asymmetric lamellar phospholipid aggregates, an oxygen carrier system which expressly contains a specified quantity of fluorocarbon, are present in an emulsified body lotion in a quantity of 10.00% (see '601 reference, column 5, lines 23-24; see also, column 6, Example 5).

Further regarding claims 27, and upon the motivation of Gross *et al.* to maintain the fluorocarbon presence as indicated successful by Stora, the skilled artisan would have been motivated to optimize the oxygen carrier presence in order to impart the desired chemical and physical properties to the final product. MPEP 2144.05 addresses the patentability of routine optimization procedure as quoted above. Likewise, the skilled artisan would have been motivated to optimize physical properties such as formulation thickness and therefore manageability by including a known gelling agent such as hydroxyethyl cellulose as is routine in the cosmetic arts and as is suggested in the disclosure of Gross

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et al., particularly since Gross *et al.* state a variety of cosmetically acceptable formulations such as gels, pastes, ointments, creams, lotions, etc (see '601 reference, column 4, lines 10-11). Similarly, the skilled artisan would have been motivated to implement jojoba oil into the topically applicable formulations on account of its commonly recognized and desirable properties such as being odorless and relatively shelf-stable when compared with other vegetable oils useful as cosmetic carriers.

Therefore, it would have been *prima facie* obvious to the skilled artisan to combine the teachings of Stora and Gross *et al.* in order to maintain the benefits of the fluorocarbon formulation component (i.e., optimized oxygen incorporation and delivery) and to further optimize this oxygen carrier component in the analogous product resulting from this combination of teachings.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stora (US 6,403,109) in view of Gross *et al.* (US 5,643,601) and Pelle *et al.* (US 5, 811,083).

The teachings of Stora are delineated above.

Stora does not disclose the inclusion of tocopherol or a tocopherol derivative in the instantly prescribed quantity.

As to claim 19, Gross *et al.* teach the inclusion of antioxidants such as α -tocopherol (see '601 reference, column 3, lines 66-67) in analogous perfluorodecalin-containing cosmetic compositions. Otherwise, the teachings of Gross *et al.* are outlined above.

Gross *et al.* do not suggest a quantity of the tocopherol for inclusion in the cosmetic composition.

Nonetheless, Pelle *et al.* specifically teach tocopherol derivatives for use in cosmetic compositions. Specifically, Pelle *et al.* disclose advantages of using tocopherol derivatives for regulating skin aging and other disorders and suggest a most preferred quantity of 0.01 to 1.0 wt. % for topical applications (see column 7, lines 32-36). Further, the skilled artisan would have been motivated to optimize this formulation component presence in order to impart desired properties to the final product. MPEP 2144.05 addresses the patentability of routine optimization procedures as quoted above.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Pelle *et al.* with the teachings of Gross *et al.* in order to determine a desirable quantity of tocopherol derivative in a cosmetic formulation. Also, it would have been *prima facie* obvious to combine the teachings of Gross *et al.* and Stora and to utilize Gross' suggestion to include tocopherol or its derivative in a topically applicable perfluorodecalin-containing cosmetic composition. One would have been motivated to combine these teachings since Gross *et al.* teaches the advantage of avoiding auto-oxidation processes in other formulation components by adding an anti-oxidant such as alpha-tocopherol to a formulation analogous to that of Stora. Since Gross *et al.* does not specify an acceptable quantity, the skilled artisan would have been motivated to look to Pelle *et al.* in order to determine a topically acceptable quantity of the tocopherol agent.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AUDREA J. BUCKLEY whose telephone number is (571)270-1336. The examiner can normally be reached on Monday-Thursday 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AJB/

/Gerald G Leffers Jr./
Primary Examiner